rejected under 35 U.S.C. 103(a) as unpatentable over DePui. It is submitted both rejections are improper and should be withdrawn.

For a reference to anticipate a claimed invention, that single reference must show each and every feature of the claimed invention arranged as in the claim. See *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193 (Fed. Cir. 1993). That reference must contain sufficient disclosure as to convince one of ordinary skill in the art that the inventor had possession of the invention at the time the reference was filed. When a composition is claimed, an anticipating reference must completely identify the claimed composition as it is set forth in the claim and must also provide an enabling disclosure so that one of ordinary skill in the art can, without undue experimentation, practice the invention. See In re Sheppard 144 U.S.P.Q. 42 (CCPA 1964). If a reference fails to properly identity the invention or to enable one to make the invention, it cannot be an anticipatory reference.

It is submitted that the DePui reference is not an anticipatory reference and therefore the rejection based on anticipation is improper and should be withdrawn.

The DePui patent, assigned to Astra-Zeneca, is directed to oral pharmaceutical dosage forms for a combined therapy against GORD (Gastro Oesophageal Reflux Disease). The dosage forms are preferably tablets containing an acid suppressing agent (proton pump inhibitors i.e. omeprazol, lansoprazol,...) and a prokinetic agent (i.e. cisapride, mosapride,...).

The main objective of DePui is an oral dosage form simultaneously containing both an acid suppressive agent and a prokinetic agent, but not enteric coating layered preparations of proton pump inhibitors.

DePui describes as obvious that the proton pump inhibitor must be protected from contact with acidic gastric juice by an enteric coating layer and specifically refers to U.S. Patent No. 4,786,505 ("the 505 patent") for omeprazole preparations (see col. 2, lines 50-57) with a description of enteric coating layered preparations of proton pump inhibitors. The '505 patent is currently being asserted by one or more companies related to Astra-Zeneca against numerous generic companies seeking to market generic omeprazole pharmaceutical preparations.

The '505 patent discloses omeprazole pellets having a core containing omeprazole and an alkaline substance, one or more separating layers, and an outer enteric coating. The separating layer(s) are described as necessary because: *"The omeprazole containing alkaline reacting cores*

must be separated from the enteric coating polymer(s) containing free carboxyl groups, which otherwise causes degradation/discoloration of omeprazole during the coating process or during storage."(see '505 col. 3, lines 4-8). U.S. Patent No. 4,853,230 (the '230 patent), also being asserted by affiliates of Astra-Zeneca, contains similar disclosure relating to other proton pump inhibitors (see col. 8, line 67 to col. 9, line 4).

Both the '505 (col. 3, lines 36 to 65) and the '230 (col. 8, lines 31 to 61) patents refer to the importance of the presence of an alkaline substance and both contain extensive disclosure as to the necessity of the separating layer because of the acid sensitivity of omeprazole and the negative experiences in bio-studies of compositions without the separating layer.

DePui fails to describe how a stable and useful oral form of a proton pump inhibitor can be made without having an alkaline reacting substance and at least one separating layer. That is to say, assuming that DePui ever contained sufficient disclosure to identify such a composition, it fails to contain enabling disclosure as to how to make such a composition.

All 14 examples described by DePui refer to a proton pump inhibitor dosage form having alkaline substance and at least one separating layer between the core and the surrounding enteric coating. The alkaline substance can be included as a basic salt of the corresponding proton pump inhibitor, i.e. omeprazole magnesium salt, as stated in the '505 (col. 4, lines 23 to 27) and '230 (col. 8, lines 55 to 61) patents. There is not a single example or suggestion of how to produce a stable and useful composition as defined in the presently pending claims.

The Examiner has referred to text regarding the enteric coating layered of proton pump inhibitors as "optional" for both the presence of alkaline reacting substances and separating layers(s). However, that disclosure is made generically and it is not supported by the cited prior art or by the patent description. Since the main object of the patent is a combined therapy for GORD, DePui sought broad protection and attempted to foreclose others from patenting a composition with no separating layer by a uninformative comment to this possibility. However, DePui fails to describe how such useful and stable enteric coating layered forms without separating layer(s) can be made.

It should be noted that none of the DePui claims specifically recite an embodiment where there is no separating layer while claim 2 does specifically recite that there is a separating layer.

The mere mention of a possible embodiment by use of a term such as "optional" may conceivably meet the "identity" prong of the anticipation requirements but cannot meet the enablement requirement. Such a mere mention is not so definite or particular that, without undue experimentation, one of ordinary skill in the art can gain possession of the claimed subject matter. See, Sheppard, supra. at page 45. Accordingly, the DePui disclosure is not enabling to prepare stable and useful proton pump inhibitor oral dosage forms without having at least a separating layer.

It is further submitted that the reference does not show the process claimed which is defined by claims 15 to 34.

Further new claim 35 defines that the composition contains a sole active ingredient. Thus, claim 35 cannot be anticipated by DePui.

It is submitted that the rejection for obviousness is also improper. Taken in its entirety, the DePui reference does nothing more propose the idea of a composition without an intermediate separating layer. However, the mere suggestion of a an idea does not render a claimed invention obvious. Once again, the cited reference does not contain sufficient enabling disclosure to suggest the claimed subject matter to one of ordinary in the art.

Consequently, based on the teachings of DePui, one of ordinary skill in the art would not have been motivated to make a composition as now claimed without the presence of a separating layer, because DePui does not teach or suggest how to make such an oral composition and both the '505 and '230 patents (owned by at least affiliates of Astra-Zeneca, if not owned by Astra-Zeneca) discourage the skilled person from trying this technical solution.

A vague uninformative disclosure coupled with prior art teaching away from the claimed invention does not establish a prima facie case of obviousness.

In view of the foregoing, reconsideration and allowance of the application with claims 1 to 13 and 15 to 35 are earnestly solicited.

It is believed that no fees or charges are required at this time in connection with the

present application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
COHEN, PONTANI, LIEBERMAN & PAVANE

By _____

Vincent M. Fazzari
Reg. No. 26,879
551 Fifth Avenue, Suite 1210
New York, New York 10176
(212) 687-2770

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